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Kieran Healy

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# DO PRESUMED-CONSENT LAWS RAISE ORGAN PROCUREMENT RATES?

*Kieran Healy\**

## INTRODUCTION

Gift-giving and voluntary donation are the standard ways of obtaining transplant organs, particularly hearts and lungs that must come from the dead.<sup>1</sup> Yet this gift-exchange does not happen everywhere in the same way or to the same extent. Despite the universality of voluntary donation, there is considerable cross-national variation in donor procurement rates. Some countries do much better than others. This variability has not received the attention it deserves, partly because the dominant ethical and policy debates focus on the relative merits of voluntary versus market systems. This has had two consequences. First, these debates tend to draw a sharp contrast between gift- and market-based systems, encouraging us to think in terms of a clear choice between the two. The assumption is that once the overall exchange system is fixed, certain consequences for the volume and composition of the supply will tend to follow, more or less directly. Second, there is a tendency for debates about *systems* to become debates about *motives*—arguments about gift versus market exchange turn into discussions of altruistic versus selfish individuals. Of course, systems and motives are not unrelated—institutions may be characterized by the incentives they provide. They may attract different sorts of individuals to participate in them, or elicit different responses from the same kinds of individuals.<sup>2</sup> But in general, an overly sharp distinction between exchange systems will tend to mislead us, as will an overly narrow focus on individual motivations. The performance of actually existing systems of organ procurement varies widely. This

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\* Sociology Department, University of Arizona; kjhealy@arizona.edu.

1. Donation is also the main source of organs from living donors, a growing illegal trade in organ sales notwithstanding. See Lawrence Cohen, *Where It Hurts: Indian Material for an Ethics of Organ Transplantation*, 128 *DAEDALUS* 135 (1999) (providing accounts of the black market in organs); Nancy Scheper-Hughes, *The Global Traffic in Human Organs*, 41 *CURRENT ANTHROPOLOGY* 191 (2000) (providing accounts of the black market in organs).

2. See generally JULIAN LE GRAND, *MOTIVATION, AGENCY, AND PUBLIC POLICY: OF KNIGHTS AND KNAVES, PAWNS AND QUEENS* (2003); Bruno S. Frey, *A Constitution for Knaves Crowds Out Civic Virtues*, 107 *ECON. J.* 1043 (1997).

Article traces this variability to its roots in structural and organizational differences between systems rather than differences in individual dispositions to give.

This Article presents a comparative study of rates of cadaveric organ procurement in seventeen countries (belonging to the Organization for Economic Co-Operation and Development, or OECD) between 1990 and 2002. Although the experiences of other countries are sometimes drawn on in debates about transplant policy in the United States, this typically happens in a piecemeal or anecdotal way. Spain is the country most commonly cited in the English-speaking literature because it has high rates of organ procurement and a different legal regime from the United States. In the "Spanish Model," presumed-consent laws nominally allow donor organs to be procured over the objections of the donor's family or next of kin. Advocates of a presumed-consent solution in the United States and Britain point to Spain's high rate of donation as evidence that such a system works, and argue that other countries have also successfully implemented this model. While these arguments rely on claims about macro-level outcomes (such as differences in procurement rates), they quickly become bioethical disagreements over the autonomy of donors and the proper role of families. The ethical issues are difficult and important, but they should not cause us to forget the underlying empirical questions. Is it really true, for instance, that presumed-consent laws elicit more donors? Do they actually work in the manner claimed by their advocates? By analyzing variation in procurement rates across countries and over time, we can make progress towards answering these questions in terms of the particular experiences of different societies.

In the process, I hope to demonstrate the value of a broadly sociological approach to questions of organ procurement and donation. Modern debate about exchange in human goods begins with Richard Titmuss's *The Gift Relationship*, the classic study of the blood supply in Britain and the United States.<sup>3</sup> Titmuss was concerned with the organizational and institutional conditions needed to ensure a safe and adequate blood supply. His argument emphasized the relationship between individual motives and the broader context of exchange, whether created by the state (in the United Kingdom) or by the presence of for-profit sales (in the United States).<sup>4</sup> But the promise of

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3. See RICHARD M. TITMUSS, *THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY* (1971).

4. Thus, for Titmuss, "the ways in which society organizes and structures its social institutions . . . can encourage or discourage the altruistic in man," *id.* at 225, and Britain's voluntary donation system allowed people to "signif[y] their belief in the willingness of other men to act altruis-

Titmuss's comparative approach was not realized in the debate that followed the book's publication. Instead, *The Gift Relationship* became best known for its main finding that altruistic donation was safer and more efficient than for-profit donation. The implicit idea that alternative ways of organizing the blood supply might lead to widely differing national outcomes—even when most systems were nominally gift-based—was not systematically pursued.

We know, however, that rates of blood and organ procurement vary widely. It is also clear that neither form of donation (especially organ donation) could happen without an elaborate organizational and institutional apparatus, regardless of the general willingness of individuals to donate. We should therefore examine the social organization of exchange in organs, focusing on how procurement agencies systematically create opportunities to give and work to produce a public understanding of why donation is worthwhile. While I develop, defend, and apply this idea at greater length elsewhere,<sup>5</sup> here I examine one aspect of it—namely the role of the legal environment in producing the organ supply. The law must obviously play *some* role—if market transfers are illegal, the law will clearly affect the composition of the supply, and perhaps also its size. In the case of cadaveric organ donation, countries differ mainly in the way the law says the consent of donors must be obtained. This Article explores how these laws affect procurement rates.

## II. THE SOCIAL ORGANIZATION OF PROCUREMENT

Cadaveric organ donation is generally thought of as a matter of individual altruism, but it can only happen in certain highly organized circumstances, subject to very tight logistical constraints. This makes it a distinctive kind of voluntary action. Despite the overwhelming emphasis on the motives and personal characteristics of individual donors and donor families, both in popular coverage of donation and the research literature, it makes more sense to treat donation as a procurement or resource-extraction problem faced by the organizations responsible for the organ supply. From this perspective, all organ procurement organizations (OPOs) face a similar set of constraints. Accident victims and other transplant candidates must be transported to hospitals quickly if they are not already there. Hospitals need to be able to deal with critically ill or brain-dead patients and quickly iden-

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tically in the future, and to combine together to make a gift freely available should they have a need for it." *Id.* at 239.

5. See KIERAN HEALY, *LAST BEST GIFTS: ALTRUISM AND THE MARKET FOR HUMAN BLOOD AND ORGANS* (forthcoming 2006).

tify potential donors. Procedures need to be in place for stabilizing the condition of donor candidates and determining that brain death has occurred. Procurement teams must be available to confirm that donation is a possibility, obtain consent from the relevant individuals (most often the next of kin), and carry out the required surgery. Once procured, organs must be distributed quickly to patients awaiting transplants. All of this must happen in a very short period of time. These demands entail a complex infrastructure, which in turn presupposes a considerable amount of investment in personnel, equipment, and organization.

While the logistical constraints are universal, each constraint opens up the possibility of variation because different organizations and health systems will produce different solutions. Medical systems will be more or less well funded and well managed; procedures will be more or less useful and followed to a greater or lesser degree; personnel will be trained in different ways or have different concerns.

Evidence of cross-national variation in donation rates is sometimes cited in public policy debates about transplantation in the United States and, recently, in Britain.<sup>6</sup> Specifically, the fact that countries with high rates of organ procurement also have presumed-consent laws is a common trope in debates about the future of organ donation. The distinction between presumed consent and informed consent is the most directly observable difference between national procurement systems. In the next section I describe these legal regimes and assess the extent of our knowledge about them. I then describe cross-national variation in procurement rates and the forces—including these laws—that might be responsible for differences between countries.

#### A. *Presumed- and Informed-Consent Laws*

The idea of presumed consent is clear enough in principle. In the absence of a clear prior statement to the contrary from the potential donor, the law assumes that consent for procurement has already been given.<sup>7</sup> Those who do not wish to be organ donors after their death must make a choice in advance to opt out of the procurement process and sign on to a central registry of nonparticipants. Procurement coordinators check this registry when faced with a potential cadaveric

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6. The Parliament in Britain recently debated the possibility of introducing a presumed-consent system. Supporters pointed to the experience of Spain and Belgium. See PARLIAMENTARY OFF. SCI. & TECH., No. 231, *Postnote: Organ Transplants* (Oct. 2004), available at [www.parliament.uk/post](http://www.parliament.uk/post) (discussing this debate).

7. The following two paragraphs sketch the general form of presumed-consent and informed-consent laws. For details on (and references to) the specific statutes in the countries under study, see *infra* tbl. 1 and accompanying notes.

donor in a hospital. The main consequence of a presumed-consent law is that there is (in principle) no need to look for evidence that the donor supported the idea of organ donation—consent is assumed, absent a recorded decision to opt out.

The most important implication of this view is that the donor's next of kin should no longer play a role in the procurement decision. In its pure form, a presumed-consent system works by taking the potential donor's decision as sovereign and then switching the "default setting" for this decision to "yes." The latter move can be justified on the utilitarian grounds that it should result in more donors. But supporters also point out that public opinion surveys typically find a high degree of support for organ donation in principle. Where no recorded objection exists—and subject to some conditions like making the option to opt out easy to pursue—it is therefore reasonable to assume that a potential donor supported the idea of donation.

In an informed-consent system such as that in the United States, by contrast, neither of these assumptions is made. Donors must opt in to the system. More importantly, even the choice to opt in (for instance, by signing an organ donor card) is generally not sufficient for procurement to take place. The consent of the next of kin or donor family is almost always required, assuming they can be found.<sup>8</sup> Refusal of consent by donor families results in a substantial loss in donated organs.<sup>9</sup> The possibility of removing the family from the decision process is therefore attractive to some transplant advocates. They argue that a presumed-consent system would better respect the wishes of the donor, as it is not uncommon for grieving families to refuse consent to donate even when there is evidence that the candidate would have wanted to donate his or her organs, especially when families do not know in advance of the prospective donor's wishes.<sup>10</sup>

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8. Since the early part of this decade, a majority of U.S. states have had "First Person Consent" (FPC) laws. These allow hospitals to proceed with procurement over the wishes of the family provided the donor has designated his or her preference on a driver's license or state donor registry. In practice, many OPOs still respect the wishes of the family, though the precise manner in which procurement teams make their requests may have become more direct since the implementation of these laws. See United Network for Organ Sharing, Donor Designation (First Person Consent) Status by State, <http://www.unos.org/resources/factsheets.asp?fs=6> (last visited Jan. 4, 2006).

9. Laura A. Siminoff et al., *Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation*, 286 JAMA 71 (2001).

10. See *id.* at 74 tbl.1. Siminoff and her colleagues found that if the donor's family *already knew* that the prospective donor carried a donor card, then the consent rate was close to ninety percent. *Id.* But if the prospective donor carried a card and the family only learned of this during the request process, almost forty percent refused consent. *Id.*

It is important to note that the role of the next of kin complicates *both* presumed-consent and informed-consent systems. A fully realized system of informed consent would employ a national “opt-in” register. Everyone would be required to make an informed decision about whether he or she wanted to become a donor if the circumstances ever arose (i.e., after death) and have it recorded and witnessed in a legally binding way. Under such a system, the next of kin’s wishes should not play a role either, as the donors themselves would have made their own decisions in advance. Signing a donor card (or a form on the back of a driver’s license) in the presence of a witness should provide enough information about the informed consent of potential donors. But in practice, the signature of the potential donor is not decisive. The United States is typical of informed-consent countries in that the donor’s next of kin will make the final decision. Although procurement coordinators may point to any available evidence about what the potential donor would have wanted, in general they will not act against the wishes of the family—even if they would technically be within their rights to do so. They fear a violent backlash against transplantation led by families whose wishes were not followed.

The organizational obstacle to a fully realized informed-consent system is that it is impractical to require everyone to make his or her choice in advance and then efficiently keep track of those decisions. Most people do not consider it likely that they will be killed in a car crash or other sudden accident. For this reason it is difficult to get people to think seriously about the issue in advance. It is also difficult to assume that their consent is fully informed in some relevant sense when they quickly fill out the paperwork while in line for a driver’s license. The Netherlands comes closest to a fully realized informed-consent system. Almost one-third of the population is on the donor registry, and recorded wishes carry more weight than the family’s objections, although the latter are still considered.

Supporters of presumed-consent laws argue that the default decision in informed-consent countries needs to be shifted. This is partly because it is more convenient to put the burden on people to opt out rather than to find a feasible way to make everyone opt in, partly because it might better respect the weight of public opinion, and partly because removing the next of kin from the consent process might boost donation rates. Advocates for presumed consent argue that other countries have successfully implemented this kind of policy. For example, the U. S.-based Presumed Consent Foundation claims: “Presumed Consent works well in other countries where it has been insti-

tuted—Austria, Spain, Portugal, Italy, Belgium, Bulgaria, France, Luxembourg, Norway, Denmark, Finland, Sweden, Switzerland, Latvia, Czech Republic, Slovak Republic, Hungary, Slovenia, Poland, Greece, and Singapore.”<sup>11</sup>

Despite these claims, systematic, comparative analysis of organ procurement rates is almost nonexistent.<sup>12</sup> It is not even clear whether presumed-consent countries really do bypass the next of kin in the procurement process. On the issue of presumed consent, then, three important questions need answering. First, which countries operate procurement systems where the law, at least nominally, implements presumed consent? Second, how do these laws work in practice? And third, how much of a country’s success in organ procurement is in fact attributable to its legal consent regime? It may be doing most of the work, or it might be that other features of a country’s institutions, the beliefs and attitudes of its population, or general environmental factors beyond the control of a procurement organization are responsible.

There is a stronger and a weaker sense in which a country might be said to have a presumed-consent system. In the stronger option, doctors would be granted two powers. First, they could presume the consent of any donor who has not formally opted out of the system in advance (by adding his or her name to a registry of nonparticipants, for instance). Therefore, no further checking into the wishes of the deceased is required. Second, once consent had been established in this way, doctors could procure organs even over the objections of the donor’s family or next of kin. In this case, the presumed-consent law simplifies the procurement process by placing the onus on potential donors to signal their unwillingness to participate *and* by removing the family from the donation process. This is the sort of law that advocates and critics generally have in mind when they discuss the possibility of introducing presumed-consent legislation in the United States.

The weaker option would only grant the first of these powers. Consent is presumed only in the sense that the default option is moved from “no” (or perhaps “ask”) to “yes.” But the next of kin still participate in the process, and may decide to veto procurement if they wish. R.M. Veatch and J.B. Pitt have argued that most presumed-con-

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11. Presumed Consent Foundation, Solutions, <http://www.presumedconsent.org/solutions.htm> (last visited Jan. 10, 2006).

12. Two notable exceptions are Ronald W. Gimbel et al., *Presumed Consent and Other Predictors of Cadaveric Organ Donation in Europe*, 13 *PROGRESS IN TRANSPLANTATION* 17 (2003), and Leo Roels & Johan De Meester, *The Relative Impact of Presumed-Consent Legislation on Thoracic Organ Donation in the Eurotransplant Area*, 6 *J. TRANSPLANTATION COORDINATION* 174 (1996).



sent systems actually take this second form, and so should be called "required request" or "routine salvaging" systems instead.<sup>13</sup> The available evidence supports this claim. Table 1 summarizes consent law and other available information about donor registration and procurement practice for seventeen OECD countries. The first column shows the nominal legal regime, as defined by each country's law governing organ donation and transplantation.<sup>14</sup> The second and third columns show available information about donor registries. Both pure informed-consent and presumed-consent systems could have full donor registries, but this is not always (or even usually) the case. No country has a fully comprehensive registry of any kind, opt-in or opt-out. The fourth column shows information on whether "required request" laws exist, and the final column shows whether the wishes of the next of kin may, in practice, determine the outcome of the procurement process.

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13. See R.M. Veatch & J.B. Pitt, *The Myth of Presumed Consent: Ethical Problems in New Organ Procurement Strategies*, 27 *TRANSPLANTATION PROC.* 1888 (1995).

14. Switzerland is the only case that is difficult to classify. While it has a national informed-consent law, a majority of Cantons (fifteen of twenty-three) have presumed-consent laws. Here I classify it with the presumed-consent countries. Blank entries mean information was not available.

TABLE 1  
ORGAN PROCUREMENT REGIMES FOR SELECTED  
OECD COUNTRIES<sup>15</sup>

Country	Legal Regime	Registry Type	Population Covered (%)	Required Request	Kin Veto
Australia	Informed	Yes	24	–	Yes
Austria	Presumed	Only No	0.05	Yes	No
Belgium	Presumed	No and Yes	2	No	Yes
Canada	Informed	Only Yes	–	–	Yes
Denmark	Informed	Yes and No	4.25	Yes	–
Finland	Presumed	–	–	–	–
France	Presumed	Only No	0.05	Yes	Yes
Germany	Informed	Pending	–	–	Yes
Ireland	Informed <sup>16</sup>	None	–	–	Yes
Italy	Presumed	Yes and No	–	Yes	Yes
Netherlands	Informed	Yes and No	29	Yes	Yes <sup>17</sup>
Norway	Presumed	None	–	–	Yes
Spain	Presumed	–	–	–	Yes
Sweden	Presumed	Yes and No	13	Yes	Yes
Switzerland	Presumed <sup>18</sup>	–	–	–	–
U.K.	Informed	Only Yes	15	No	Yes
U.S.A.	Informed	Only Yes	–	Yes	Yes

All informed-consent countries have an effective kin veto, regardless of their donor registry system. It turns out, however, that the same is true of almost all presumed-consent countries. They, too, generally allow the family to refuse consent. Austria is the only country with a strong-form presumed-consent system, where family or next of kin have no involvement in the procurement decision.<sup>19</sup> After Aus-

15. The information from Table 1 was compiled from various sources. See WORLD HEALTH ORGANIZATION, *LEGISLATIVE RESPONSES TO ORGAN TRANSPLANTATION* (1994); H. Gäbel, *Donor Registries Throughout Europe and Their Influence on Organ Donation*, 34 *TRANSPLANTATION PROC.* 997 (2003); Gabriele Wolfslast, *Comparative European Legislation on Organ Procurement*, 13 *BAILLIERE'S CLINICAL ANAESTHESIOLOGY* 117 (1999); see also national organ donation agency websites.

16. Ireland has adopted informed consent, but has no law requiring such a policy.

17. If a donor is registered, the family's wishes carry less weight.

18. See *supra* note 14.

19. See R.D. Fitzgerald et al., *Support for Organ Procurement: National, Professional, and Religious Correlates Among Medical Personnel in Austria and the Kingdom of Saudi Arabia*, 34 *TRANSPLANTATION PROC.* 3042 (2002); see also Maureen McCunn et al., *Impact of Culture and Policy on Organ Donation: A Comparison Between Two Urban Trauma Centers in Developed Nations*, 54 *J. TRAUMA INJ. INFECTION & CRITICAL CARE* 995 (2003).

tria, Belgium's practices are the next strongest. It has a strong presumed-consent system which nevertheless does allow the next of kin a role in the procurement process.<sup>20</sup> In other countries—notably France, Norway, Sweden, and Italy—the *de jure* presumed-consent system still nevertheless allows a *de facto* kin veto.

Table 1 shows right away that the most straightforward story about presumed consent cannot be true. If almost all presumed-consent countries in fact allow the next of kin to refuse consent for donation, then any success in procurement cannot be due simply to a law that permits doctors to override the wishes of families during the donation process. With this in mind, we can still ask whether it is in fact the case that presumed-consent countries do better than informed-consent countries. Presumed-consent laws may still play an important role, even if it is not the one advocates imagine.

### B. Cross-National Trends in Procurement Rates

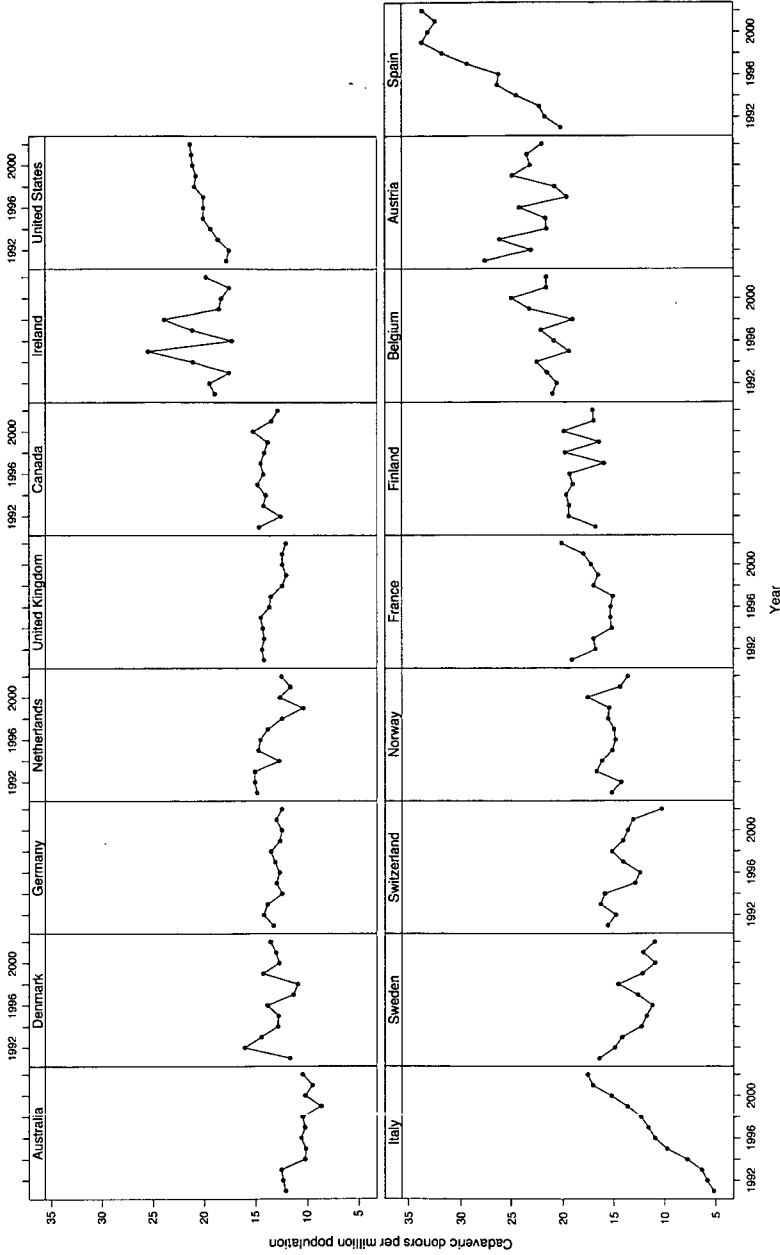
Procurement rates show substantial cross-national and longitudinal variation. Figure 1 shows the number of cadaveric donors per million population for seventeen, advanced capitalist democracies between 1990 and 2002. Countries with informed-consent laws are shown in the top row and presumed-consent countries are on the bottom. Countries are organized by average procurement rate in each row, from lowest to highest reading left to right. The scale of each panel in the figure is the same, so trends are directly comparable across countries.

National procurement rates vary in the *volatility* of the time trend (its tendency to bounce around from year to year), the pattern of *relative growth or decline* over time, and the *overall average rate* observed. Larger countries (e.g., the United States, Britain, and Germany) show less volatility from year to year than smaller countries (e.g., Ireland and Belgium). Between one-third and one-half of the countries show a relatively flat profile or a slight decline over the period: Australia, Germany, the United Kingdom, and Canada are most clearly in this category, with Denmark, Ireland, and Finland showing more volatility from year to year around a more or less unchanging mean. Procure-

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20. See Letter from L. Roels, Transplant Coordinator, Univerity Hospital Gasthuisberg, to *bmj-journals.com* (July 27, 1998) (available at [http://bmj.bmjournals.com/cgi/content/full/318/7180/399/a?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=Roels&andorexactfulltext=and&searchid=1138204591124\\_10914&FIRSTINDEX=0&sortspec=relevance&resource type=1](http://bmj.bmjournals.com/cgi/content/full/318/7180/399/a?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=Roels&andorexactfulltext=and&searchid=1138204591124_10914&FIRSTINDEX=0&sortspec=relevance&resource type=1)); L. Roels et al., *Three Years of Experience With 'Presumed Consent' Legislation in Belgium: Its Impact on Multi-Organ Donation in Comparison With Other European Countries*, 23 *TRANSPLANTATION PROC.* 903 (1991).

FIGURE 1



Procurement rates per million population, 1990–2002, for seventeen OECD countries. Informed-consent countries are shown in the top row; presumed consent in the bottom row. Rows are ordered from lowest to highest median procurement rates.

ment rates in the Netherlands, Sweden, Switzerland, and Norway tend to decline over time, though each of the latter three countries experiences a short period of growth in the late 1990s that does not seem to have been sustained in more recent years. By 2002, the procurement rate in each of these countries had fallen back to or below the starting point in 1990. In France, rates decline until 1997 and then steadily increase thereafter. The United States shows slow but consistent growth over the whole time period. The two most striking cases are clearly Italy and Spain. Both of these countries show continuous, rapid growth over the whole period. The main difference between them is that Spain begins with the highest procurement rate (by far) while Italy is initially the poorest performer after Australia.

Comparing the top and bottom rows of Figure 1 suggests that average procurement rates tend to be a little higher in countries with presumed-consent legislation than in those with informed-consent rules. What might explain this difference? And what other factors should predict national procurement rates?

### *C. How Might Presumed-Consent Laws Affect Procurement Rates?*

There are three ways that presumed-consent laws might be associated with higher procurement rates. First, and most significantly, presumed-consent laws may allow for the next of kin's wishes simply to be ignored in the procurement process, causing all potential donors to become actual donors, with no loss due to refusals by the next of kin. We now know, however, that this cannot be the right explanation. Almost all countries with presumed-consent laws allow for the next of kin to be consulted and even to have a deciding say. Austria is the only true exception, and perhaps also Belgium to a lesser degree. Outside of Austria, any effect presumed-consent laws have cannot be due to them removing families from the procurement process.

This does not mean these laws have no effect. A second possibility is that presumed-consent laws function as a signaling device to the population in general and next of kin in particular. Having a presumed-consent law shifts the question facing donors and especially their families. Rather than being asked, "Can we have your permission to go ahead?" families are instead asked something like, "Do you have any reason to think the donor would have objected?" This is a small but significant shift. With respect to public opinion, in such a system presumed-consent laws would express a social norm or collective expectation about the default course of action. Donation is still a choice, but saying "yes" is assumed to be the standard option, rather than a special decision for which consent must be specially sought. In

the context of actual procurement requests, this means that the next of kin retain the right to object, but their role in the decision process is somewhat different. They must actively throw up an objection rather than be approached as the sole arbiters of the outcome.

In the United States, the phrase “presumed consent” strongly connotes that the next of kin’s wishes can be ignored or overridden, and so this weaker interpretation might not seem to qualify as a presumed-consent system at all. But, as Michael B. Gill argued, it does articulate an important position, neglected in the United States debate, that falls between strong-form presumed consent and the much weaker notion of a required-request rule.<sup>21</sup> A required-request system simply obliges procurement coordinators to follow up on every potential donor. From the next of kin’s point of view, the burden of expectation is not shifted in any way.<sup>22</sup> Gill argued that there ought to be a presumption *on everyone’s part* (a social norm, in other words) that organs should be donated, even if the family still has the right to object.<sup>23</sup> This does indeed shift the burden of expectation on families and may make consent easier to obtain from families as a result.

The third reason that presumed-consent laws might be empirically associated with higher procurement rates is because both are associated with some other important factor. Rather than being a causal force in themselves, or the formal expression of an effective norm, it might be that presumed-consent laws are simply a marker for other practices that make organ procurement more efficient. We know from the United States case that procurement organizations with more resources and wider reach have higher procurement rates.<sup>24</sup> The historical development of transplant programs is often associated with the work of organizational entrepreneurs (usually the transplant surgeons) who mobilize resources in an effort to secure as many organ donors as possible for the transplants they want to perform.<sup>25</sup> When transplant advocates reorganize or expand a transplant system, they are likely to invest in its infrastructure and personnel—providing new facilities, more training, and so on—while also organizing publicity

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21. See Michael B. Gill, *Presumed Consent, Autonomy, and Organ Donation*, 29 J. MED. & PHIL. 37 (2004).

22. Indeed, required request laws were instituted in the United States in the 1980s to overcome reluctance on the part of *medical staff* to ask about procurement, not to better encourage next of kin to say “yes.”

23. See Gill, *supra* note 21, at 55.

24. See Kieran Healy, *Altruism as an Organizational Problem: The Case of Organ Procurement*, 69 AM. SOC. REV. 387, 387 (2004).

25. See ROBERTA G. SIMMONS ET AL., GIFT OF LIFE: THE SOCIAL AND PSYCHOLOGICAL IMPACT OF ORGAN TRANSPLANTATION (1997).

campaigns and public policy initiatives. Presumed-consent legislation might be a byproduct of such efforts, and might be the most visible external marker of them, without itself contributing much to any subsequent increase in procurement rates. In such circumstances, we would still expect presumed-consent countries to do better than informed-consent countries, but not because the law is directly intervening in decisionmaking by donors. Rather, it is a proxy for other factors that make a difference.

#### *D. Other Factors Affecting Procurement Rates*

Procurement rates are influenced by structural and organizational forces other than the law. On the supply side, cadaveric organ procurement is naturally limited by the supply of potential donors. Potential donors are people who die in circumstances that make donation possible in principle. Not all causes or circumstances of death yield a potential donor. Many diseases rule candidates out of consideration. Potential donors come most often from deaths caused by cerebrovascular diseases (such as strokes or aneurysms) or road accidents.<sup>26</sup> Other trauma cases, such as deaths due to falls, drowning, or assault, are also a source of potential donors. Procurement organizations do have some leeway at the margins: better-resourced systems will be more able to locate road accident victims in time and stabilize them in the hospital, for instance. But if a country simply has a lower rate of road accident fatalities than average, or a higher rate of deaths from cerebrovascular diseases, we should expect the procurement rate to vary accordingly, all other things being equal.

In addition to these exogenous effects, organ procurement organizations and transplant centers are part of wider systems of healthcare. Features at both the organizational and macro-institutional levels should affect procurement rates. The structure, staffing, and resources of procurement organizations are vitally important aspects of the transplant system, and evidence from the United States case suggests these features may be the most important determinants of the procurement rate.<sup>27</sup> We cannot easily measure these variables across

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26. For data on causes, circumstances, and mechanisms of death, see Organ Procurement and Transplantation Network, Data, <http://www.optn.org/data> (last visited Jan. 25, 2006). In 2005, 20.1% of recovered donors died in a motor vehicle accident (MVA), the largest single category outside of "natural causes" (28.8%); 43.5% suffered a stroke or other cerebrovascular injury. *Id.* Note that MVAs are a *circumstance* of death while cerebrovascular injuries are a *cause*, so the two figures should not be combined. MVA deaths are generally caused by head trauma injuries, which accounted for 38.7% of donor deaths in 2005.

27. See HEALY, *supra* note 5; Healy, *supra* note 24, at 393–94.

countries or over time. We can, however, control for some broader features of each society that might be correlated with procurement.

Most simply, a country's per capita GDP ought to be positively associated with the procurement rate. Transplantation is carried on mainly in wealthy countries, and the necessary infrastructure is expensive to support. More specifically, we might also expect a country's healthcare system and its level of healthcare spending to affect procurement rates. But the direction of the relationship is not clear. Two opposing possibilities suggest themselves. The first is that an inclusive public healthcare system is a prerequisite for high procurement rates. The idea is that the ultimate reliance of transplant systems on the gifts of donors is more likely to be successful where there is a strong, collective commitment to public health. The generalized reciprocity that donation depends on—gifts from anonymous donors to unknown recipients—might be more easily sustained in the context of a national health service of some kind. This was a key part of Richard Titmuss's argument in *The Gift Relationship*.<sup>28</sup>

Alternatively, it might be that a strong commitment to publicly funded healthcare is associated with *lower* rates of organ procurement, given the expensive and selective nature of donation. Organ transplantation has become quite widespread in the past twenty years and is poised for continued growth (or at least increasing demand).<sup>29</sup> But the cost and difficulty of the operation, and the life-long post-transplant care needed by recipients, mean that transplantation is not by any measure a form of basic healthcare. This suggests that while wealthier countries should have higher procurement rates, high levels of public spending on healthcare might be negatively associated with higher procurement rates.

As this last point implies, the organizational and legal details of organ procurement are embedded in broader institutional and cultural features of societies, not just the healthcare system. The form and extent of logistical support for donation will have evolved within particular systems of healthcare provision. Similarly, legal regimes governing transplants will not have emerged in a vacuum. Cases like Japan, where transplants were taboo for many years, show that cultural context can matter a great deal.<sup>30</sup> Historical legacies in Ger-

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28. See TITMUSS, *supra* note 3.

29. Since 1988, the number of individual patients on the waiting list for a transplant has grown by an average rate of about ten percent per year. I arrived at this result by calculating the numbers provided in the Organ Procurement and Transplant Network Annual Reports for 1998 and 2004.

30. See Margaret Lock, *Deadly Disputes: Ideologies and Brain Death in Japan*, in ORGAN TRANSPLANTATION: MEANINGS AND REALITIES 142 (Stuart J. Younger et al. eds., 1996).



many have also made transplantation a complex public issue.<sup>31</sup> I will not pursue this question further here, though it certainly merits closer analysis. For present purposes, our goal is to estimate the contribution of a country's legal regime to its procurement rate. We will do this while controlling for two of the major inputs to the supply of potential donors—death rates from road accidents and cerebrovascular diseases—on the one hand, and two measures capturing the overall wealth and commitment to public health spending for each country, on the other.

### III. DATA AND METHODS

The dependent variable for the quantitative analysis is the number of cadaveric donors procured per million population for each of seventeen OECD countries between 1990 and 2002. These data were provided by Transplant Procurement Management (2004) and national organ procurement agencies. The independent variables—covering the same countries and time period—are the per capita GDP (measured in dollars purchasing power parity), public health expenditure as a percentage of GDP, the road accident fatality rate (per million population), the death rate from cerebrovascular disease (per million population), and the country's classification as a presumed-consent or informed-consent regime. Figure 2 summarizes information about the distribution of these variables.

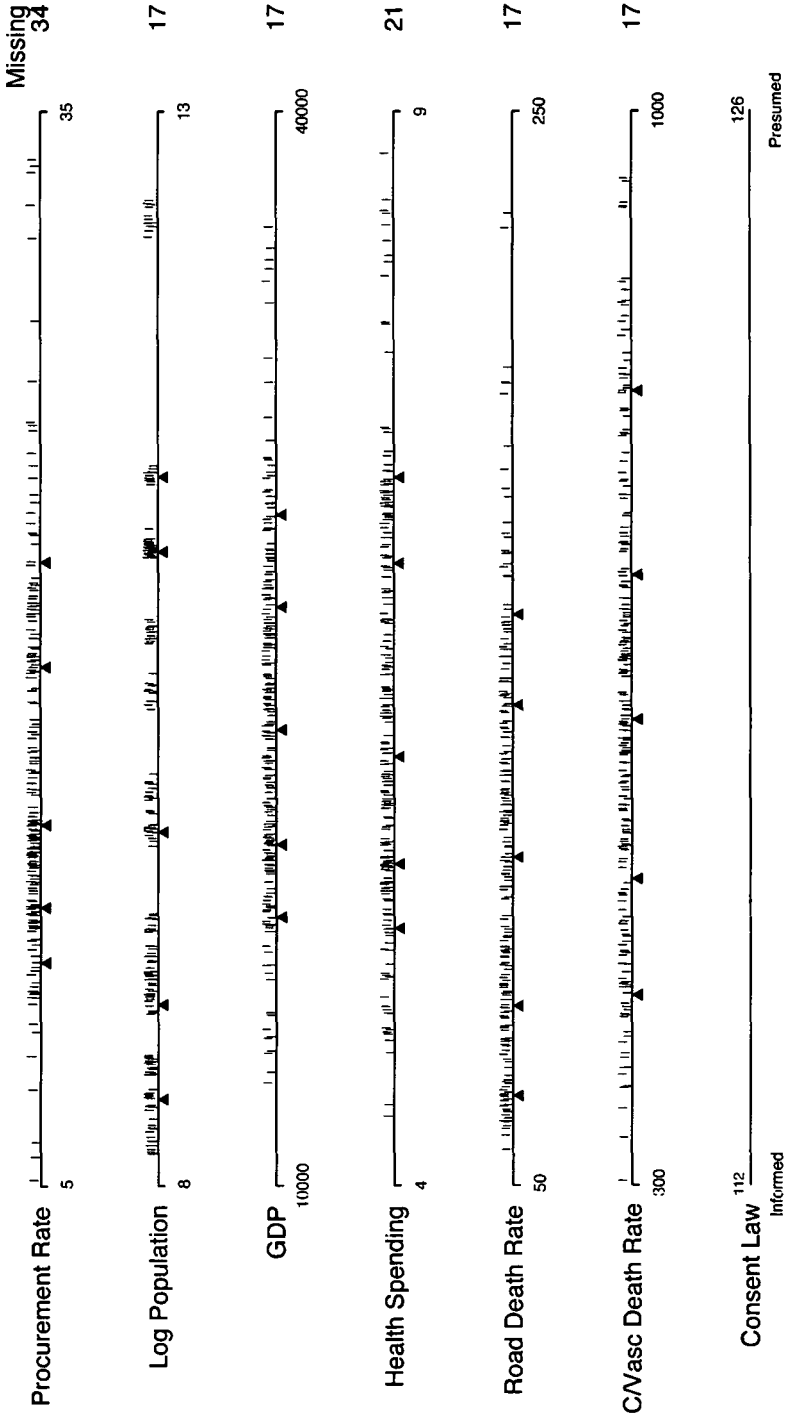
Most countries can be easily assigned to a legal regime, having passed the relevant legislation prior to the period under analysis. Some countries passed new legislation between 1990 and 2002 that reaffirmed or expanded the existing legal status of transplantation: France and Italy passed new presumed-consent laws in 1990 and 1999, respectively, superseding older presumed-consent laws dating from the mid-1970s. Similarly, Germany passed new informed-consent legislation in 1997 that continued its existing practices. As noted earlier, Switzerland is classified as a presumed-consent country.

The cross-sectional, time-series structure of the data makes regular ordinary least squares (OLS) methods inappropriate due to the clustering of observations at the country level and the serial correlation of within-country observations over time. Consent laws do not vary within countries over the observed time period, so a fixed-effects formulation is not applicable. In addition, there are likely to be unobserved factors affecting the donation rate within each country. Both

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31. See LINDA F. HOGLE, *RECOVERING THE NATION'S BODY: CULTURAL MEMORY, MEDICINE, AND THE POLITICS OF REDEMPTION* (1999).

FIGURE 2



The distribution of country-year observations for 1990 to 2003 is shown for each variable. For continuous variables, observations are represented by tick marks above the scale line. Triangles below the line indicate the values of the 10th, 25th, 50th, 75th, and 90th percentiles.

of these features make a hierarchical (or mixed-effects) model the natural specification, with a random effect for each country. This model takes the following form (Equation 1):

$$y_i = X_i\beta + Z_i b_i + \varepsilon_i, \quad i = 1, \dots, M,$$

where  $y_i$  is the  $n_i \times 1$  vector of donation rates in the  $i$ th country,  $X_i$  is the  $n_i \times p$  model matrix for the fixed effects for observations in country  $i$ ,  $\beta$  is the vector of fixed-effect coefficients,  $Z_i$  is the  $n_i \times q$  model matrix of random effects for observations in country  $i$ , and  $b_i$  is the  $q \times 1$  vector of random-effect coefficients for country  $i$ . The random-effects coefficients are assumed to be distributed as follows (Equation 2):

$$b_i \sim N_q(0, \Psi),$$

where  $\Psi$  is the variance-covariance matrix for the random effects. The error term in Equation 1,  $\varepsilon_i$ , is characterized as follows (Equation 3):

$$\varepsilon_i \sim N_{n_i}(0, \sigma^2 \Lambda_i), \quad i = 1, \dots, M,$$

where  $\sigma^2 \Lambda_i$  is the covariance matrix for the errors in country  $i$ . Because the within-country observations are an annual time series, the error structure is given by the first-order autoregressive process, AR(1) (Equation 4):

$$\varepsilon_t = \phi \varepsilon_{t-1} + a_t,$$

where the current observation's error term is a linear function of the previous observation,  $\phi \varepsilon_{t-1}$ , plus a normally distributed noise term,  $a_t$ .

Alternative model formulations (notably pooled time series or generalized least squares approaches) are also plausible, but are not presented here. In a generalized least squares model, no country-level random effect would be specified. Instead, the serial correlation of the data and the within-country variance would be incorporated into the error structure of the model. This approach gives what seem like overly optimistic estimates of the fixed effects. Exploratory analysis suggests that there is a high degree of within-country variation that is not explained by our measures of death rates, GDP, or spending. As we have seen, there is little existing research on the cross-national determinants of organ donation, and such research as is available suggests that subnational and organizational-level factors will matter a great deal. The best methodological strategy is to incorporate the likely presence of country-specific factors into the model as directly as possible. The mixed-effects approach allows us to do this in a convenient way. It may produce more conservative estimates of the fixed-effects we are interested in (such as the presence of presumed-consent

laws) than other specifications, but it better reflects the nested process that generates the data we observe.<sup>32</sup>

#### IV. RESULTS

Fixed-effects coefficients for a linear mixed-effects model are presented in Table 2. Although the signs of the coefficients are in the expected direction (with the exception of cerebrovascular deaths), none are statistically significant. The effect of presumed-consent laws is relatively large in magnitude, but is not statistically significant. These weak results are somewhat surprising. Further exploration of the model reveals that it does not fit the data well, and for a specific reason. By examining a plot of the standardized residuals by country (the left-hand panel of Figure 3), we can see that the observed data from Spain and Italy are poorly explained by the model.<sup>33</sup> These are, of course, the only two countries that have shown sustained, rapid growth in their procurement rates through the 1990s. This makes their profile quite different from other countries in the dataset—particularly the larger ones, which show comparatively modest patterns of growth or decline. Our country-level predictors of procurement do poorly as a consequence. This suggests that it is worth treating the outlying cases separately. Before we examine these two cases in more detail, we can look again at our model with Spain and Italy excluded from the dataset.

TABLE 2  
FIXED-EFFECTS COEFFICIENTS FROM A LINEAR MIXED-EFFECTS MODEL OF DONOR PROCUREMENT

	Value	Std.Error	DF	t-value
(Intercept)	14.706	1.42	180	10.33
GDP	0.005	0.00	180	0.40
Health	-0.683	0.53	180	-1.29
Roads	0.018	0.02	180	1.17
C/Vasc	-0.004	0.00	180	-0.79
Presumed Consent	3.185	1.97	15	1.62

AIC: 885.5. BIC: 914.9. Log-likelihood: -433.7. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by one hundred.

32. See generally JOSÉ PINHEIRO & DOUGLAS M. BATES, MIXED EFFECTS MODELS IN S AND S-PLUS (2000). The models were fit using restricted maximum likelihood with the "nlme" library. Figures were produced with Deepayan Sarkar's Lattice Graphics and Frank E. Harrell's Hmisc: Harrell Miscellaneous software packages for R.

33. The residuals can be thought of as reflecting the difference between what the model predicts and what we actually observed. Standardized residuals ought to be evenly distributed around zero for each country. If they are not, this is evidence that the model does not fit the data for that country very well.

TABLE 3  
FIXED-EFFECTS COEFFICIENTS FROM A LINEAR MIXED-EFFECTS  
MODEL OF DONOR PROCUREMENT, ITALY AND SPAIN EXCLUDED

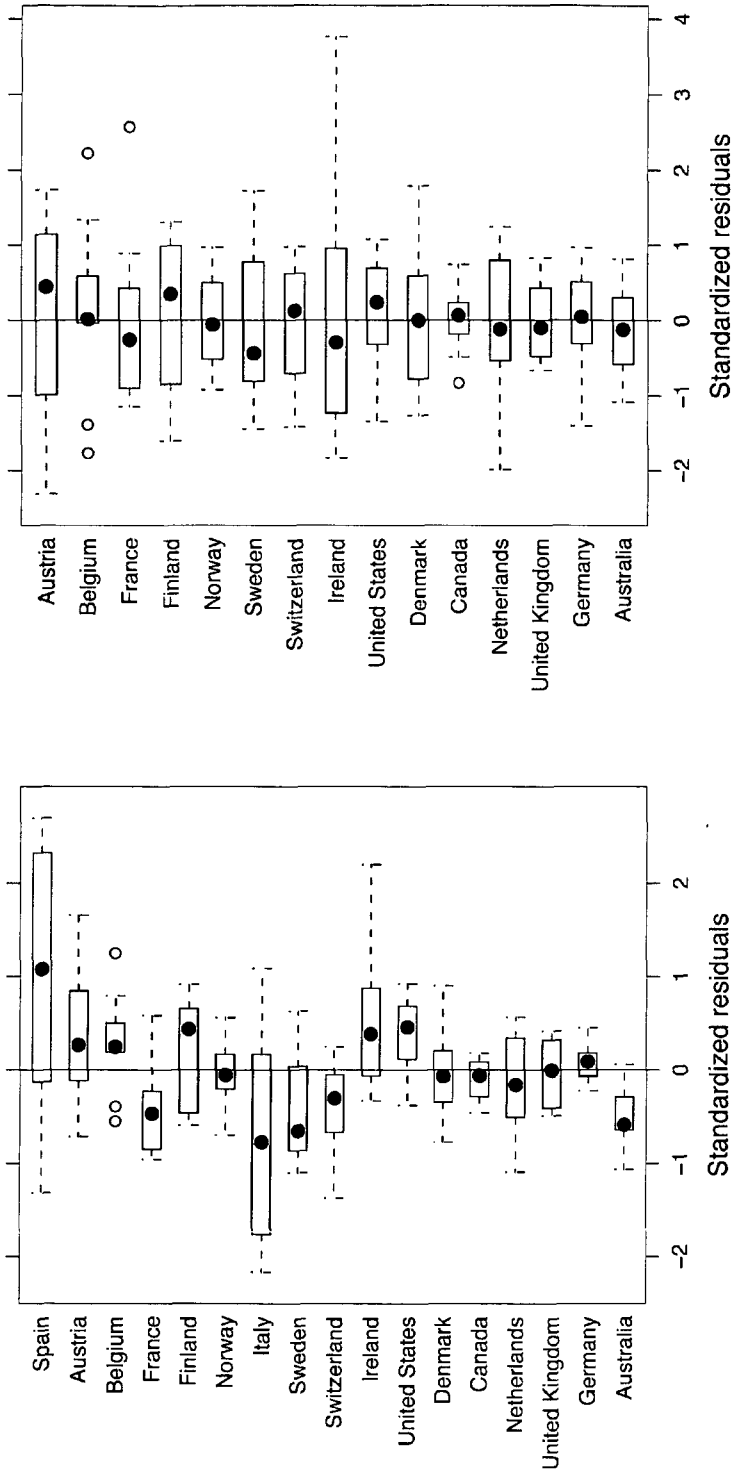
	Value	Std.Error	DF	t-value
(Intercept)	15.131	0.89	158	16.92
GDP	0.012	0.00	158	2.03
Health	-0.590	0.33	158	-1.79
Roads	0.036	0.01	158	3.19
C/Vasc	0.006	0.00	158	2.03
Presumed Consent	2.516	1.31	13	1.93

AIC: 736. BIC: 764.3. Log-likelihood: -359. Country-level random effects fitted but not shown. Variables are centered on their means. GDP coefficient is multiplied by 100.

Table 3 shows the fixed-effects coefficients for the same model as before, this time excluding data from Spain and Italy. The results are a good deal better—GDP, road fatalities, and cerebrovascular deaths all have positive and significant effects on the procurement rate, as predicted. Road fatalities make a much larger contribution to the procurement rate than do deaths from cerebrovascular diseases. This may be because road accident victims are converted into donors more efficiently. Although not quite significant at conventional levels, the negative effect of health spending is quite large—a two-point change in health spending as a percentage of GDP is associated with roughly a one-point drop in the procurement rate. The effect of the legal regime is also large. A presumed-consent regime is worth an additional 2.7 donors per million population, when other variables are at their mean values. The right-hand panel of Figure 3 confirms that the model fits the data better with Spain and Italy excluded.

This analysis first suggests that when all of the available data is taken into account, the presence of presumed-consent laws does not make a material difference to the procurement rate one way or the other. But the analysis is not unique in this regard—other variables expected to be positively associated with the procurement rate have no measurable effects either. On the other hand, the presence of two countries with rapidly growing procurement rates makes the statistical model fit quite poorly. If Spain and Italy are set aside, our model does better. The “supply-side” measures of the death rate are positive and significant (particularly the road fatality rate). Richer countries procure more donors, in line with our expectations. Countries with a higher share of public health spending seem to procure fewer donors. The effect of presumed-consent laws is positive, though neither of these effects is strongly significant at conventional levels.

FIGURE 3



Distribution of standardized residuals by country for a model including Spain and Italy (left) and the same model excluding Spain and Italy (right). Residuals ought to be evenly distributed around zero.

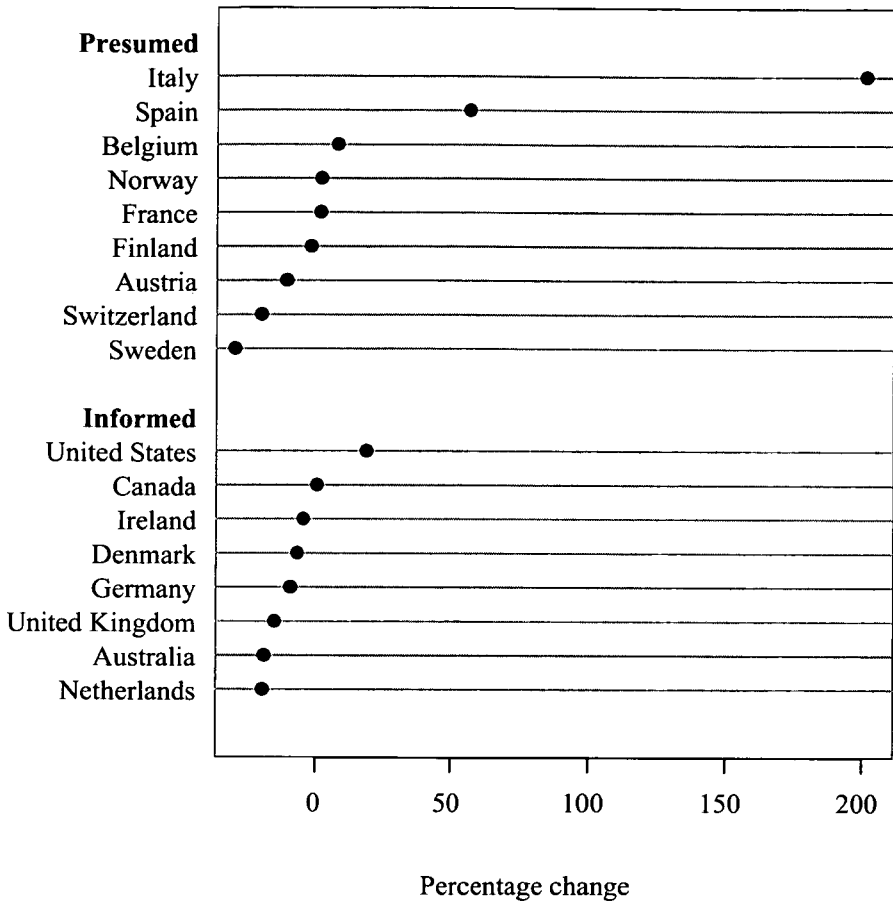
### A. *Spain and Italy*

If we focus on the overall percentage change in the procurement rate over the past twelve years, the distinctive status of Spain and Italy becomes very clear. Figure 4 shows the percentage change in the procurement rate for each country by taking the mean procurement rate from 1990–1994 as the start point and the 1998–2002 mean rate as the end point. Countries with zero net change score a zero in this figure. The median change across all countries was a *decline* in the average procurement rate of about 4.75 percent. Half the countries fall somewhere between a decline of about fifteen percent and an increase of about two percent. Countries showing only modest growth or a net decline are split more or less evenly between presumed- and informed-consent regimes. As the more formal model confirms, presumed-consent countries may do slightly better on the average, but in general the differences are small. The biggest losers are Switzerland and Sweden among presumed-consent countries, and Australia and the Netherlands among informed-consent countries. Procurement rates in all four of these countries declined by about twenty percent from the early 1990s to the early 2000s. By contrast, Belgium (presumed consent) and the United States (informed consent) show fairly steady growth. But the cases of Spain and especially Italy stand out here, with growth rates far greater than any other countries. Spain has long been known for its successful organ procurement program. Already a leader at the beginning of the 1990s, it procured fifty-five percent more organs at the end of the period than it did at the beginning. Italy's growth—about 175 percent over the period—has been astonishing. Unlike Spain, it began the 1990s as one of the poorest-performing countries, but by 2002 had moved to the upper half of the distribution.

Spain successfully reorganized its procurement system in the early 1990s and has seen a substantial increase in donation rates since then. It is the country most frequently cited as the exemplary presumed-consent regime—the “Spanish model.” Its continued growth is not easily explained in terms of the unchanging laws governing donation. The evidence strongly suggests that other factors are responsible for this success and shows decisively that the strongest form of presumed consent (with no next-of-kin veto) is not practiced. Instead, investment in hospitals and procurement organizations is responsible for the sustained growth. R. Matesanz and colleagues discussed the overhaul of the Spanish system:

In each potential donor hospital there is a transplant coordination team that is responsible for the whole process of organ procure-

FIGURE 4



Percentage change between the average procurement rate at the beginning of the period (1990-1994) and the end of the period (1998-2002).

ment, from the detection of the donor to the organ grafting or tissue banking. Annual rate of cadaveric donors rose from 14.3 per million population (pmp) in 1989 to 21.7 donors pmp in 1992. Organ retrieval rate increased by 81% during the same period. Renal, liver and cardiac transplants increased by 44%, 175% and 162% respectively. We conclude that this particular approach to the problem has been successful in Spain, overcoming obstacles such as untrained or undertrained requesting staff, unidentified donors, and reluctance to approach grieving families.<sup>34</sup>

A more recent account by this author confirms this view, emphasizing the positive effects of training and organizational innovation in

34. R. Matesanz et al., *Organ Procurement in Spain: Impact of Transplant Coordination*, 8 CLINICAL TRANSPLANTATION 281, 281 (1994).



improving the consent rate: a proactive donor detection program performed by well trained transplant coordinators, the introduction of systematic death audits in hospitals, and the combination of a positive social atmosphere with adequate economic reimbursement for the hospitals have accounted for this success.<sup>35</sup>

Similarly, George J. Chang and colleagues described the success of the Spanish Model not in terms of presumed-consent laws but as a matter of organizational innovation:

The so-called "Spanish Model" has been outlined as a structure of national, regional, and local or in-hospital efforts to increase organ donation. The management structure consists of a front-line in-hospital transplant coordinator who is fully involved and accountable for the donor recruitment effort. Furthermore, transplant donor coordination has been "professionalized" and most coordinators are qualified doctors, mainly intensive care specialists and nephrologists, who have dedicated time allocated to transplant coordination. Moreover, the Spanish system adheres to the principles of decentralization of the donor coordination effort through the use of regional coordinators and the establishment of organ procurement as the main priority for national, regional, and hospital coordinators.<sup>36</sup>

Chang found that a substantial portion of the improvement in donation rates in Spain is due to increases in the use of older donors who previously would not have been considered viable candidates for procurement. A study by J. Rosel and colleagues tried to identify "variables [that influenced] a family member's decision to donate."<sup>37</sup> They found that for seventy-one cases in hospital in Malaga, the "the manners and approach of the doctors" to the donor families played a significant role in obtaining consent from donor families. Matesanz described the system in further detail:

The Spanish Model also includes a great effort in continuous medical training and education for new and old transplant coordinators financed and directed by the central Health Administration, including various training programs for health professionals, specifically dedicated to every step of the process (donor detection and management, legal aspects, family approach, organizational aspects, management of resources, and so on).

. . . . Spain has a theoretical presumed consent law, but, from a practical point of view, family consent is always requested and the

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35. R. Matesanz, *A Decade of Continuous Improvement in Cadaveric Organ Donation: The Spanish Model*, 21 NEFROLOGIA 59 (2001).

36. George J. Chang et al., *Expanding the Donor Pool: Can the Spanish Model Work in the United States?*, 3 AM. J. TRANSPLANTATION 1259, 1259 (2003) (internal citations omitted).

37. J. Rosel et al., *Discriminant Variables Between Organ Donors and Nondonors: A Post Hoc Investigation*, 90 J. TRANSPLANT COORDINATION 50, 50 (1999). Similar studies have been carried out in the United States. See, e.g., Siminoff et al., *supra* note 9.

wishes of the relatives are always respected, as happens in practically all European Union countries. In fact, family refusal rates have remained stable between 20% and 25% during the last few years. What is clear is that the increased organ donation during the 1990s cannot be attributed to any change in Spanish legislation, which has remained unmodified since 1979[.]<sup>38</sup>

Reports of the Spanish case strongly suggest that improved donation rates are due to substantial investment in the logistics of organ procurement—better training, clear delegation of responsibility, a strong presence in hospitals—rather than a change in the legal definition of donation or an unprompted sea change in public opinion. Consent laws are not responsible for Spain's high rate of organ donation.

Italy's experience is less well documented, in part because the rapid rise in its procurement rate has been a more recent phenomenon than in Spain. The available sources make it clear, however, that regional transplant authorities in Italy have explicitly copied the Spanish approach to procurement, with similar results. Matesanz argued that "Italy has probably been the country that has adopted more elements of the Spanish Model and worked more seriously in this direction" than any other.<sup>39</sup> Bruno Simini reported that:

Tuscany alone doubled its organ donation rate to 26.9 dpmi in the space of just one year. "Tuscany", said [transplant director Alessandro] Nannicosta, "achieved in one year what northern regions achieved in 4 or 5 years, after adopting the Spanish model for organ donation". This model relies upon "local transplant co-ordinators and excellent training of all staff involved."<sup>40</sup>

Data on regional trends within Italy bear out these reports. Growth in the procurement rate since 1999 has been unevenly distributed within the country. Southern regions have performed significantly worse than northern ones on the average. Procurement rates in northern provinces such as Piemonte or Emilia-Romagna are typically twice or even three times as high as those in Calabria or Sicily.<sup>41</sup> Amongst the central regions, Tuscany, Marches, and also Sardinia in-

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38. R. Matesanz, *Factors That Influence the Development of an Organ Donation Program*, 36 *TRANSPLANTATION PROC.* 739, 740 (2004).

39. *Id.* at 741.

40. See Bruno Simini, *Tuscany Doubles Organ-Donation Rates by Following Spanish Example*, 355 *THE LANCET* 476 (Feb. 5, 2000). Similarly, Bozzi and colleagues described part of Tuscany's pilot program as "based on a database elaborated by the Transplant Coordination Office of the Pisa University, according to the Spanish program of the National Transplant Organization." G. Bozzi et al., *Summary: The Quality Improvement Program in Organ Donation of the Tuscany Region*, 36 *TRANSPLANTATION PROC.* 424 (2004).

41. See Associazione Italiana per la Donazione di Organi, Tessuti e Cellule, <http://www.aido.it> (last visited Nov. 17, 2005) (providing regional data).

creased their procurement rates rapidly between 2000 and 2003.<sup>42</sup> The results of the quantitative analysis, together with more detailed reports about individual countries, suggest that overall average levels of organ donation are partly explained by supply-side considerations and stable structural features of societies (perhaps including the nominal legal regime governing procurement). At the same time, dynamic growth in procurement rates depends mainly on “middle-range” changes, notably infrastructural investment and organizational reform.

## V. CONCLUSION

Cadaveric organ procurement is a complicated kind of gift, because the next of kin or family are the *de facto* givers. Faced with this fact, presumed-consent laws have been an attractive solution to some because they promise to remove the next of kin from the decision and so guarantee a boost in the procurement rate. There has been considerable debate about the ethics of this policy, speculation about a possible backlash in public opinion should it be implemented, and anecdotal evidence about its success in other countries. Yet there has been virtually no research on whether these laws work as advertised. As this Article has shown, presumed-consent laws typically do not remove the next of kin from the procurement process. In all but one or perhaps two cases in western countries, the family’s right of refusal is retained. This fact alone vitiates the standard case for presumed consent, at least insofar as it credits higher procurement rates to the elimination of the next of kin’s veto. Yet there is more to the problem than this. Presumed-consent countries do in fact perform a little better on average than informed-consent countries. I have argued that this is not because of any direct effect of the law on individual choices. Rather, countries with presumed-consent laws are more likely to have paid close attention to the social organization of their transplant systems. High-yield cases like Spain and Italy stand out not because their legal systems mandate a different kind of choice for donors, nor because they offer some special incentives for donor families or next of kin. Instead, they have invested effectively in the logistics of the transplant system: they put more staff on the ground, trained them better (especially in the crucial process of requesting consent from families), and improved coordination between the different actors and agencies in the procurement process. Recent research shows that similar reforms may boost donation rates in United States organ procurement organi-

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42. *Id.*

zations.<sup>43</sup> This result is encouraging—it suggests that there is room for programs to improve their performance. Organizations are easier to change than baseline death rates, the entire healthcare system, or the cultural traditions of a whole country.

The organizational underpinnings of donor procurement have been neglected in debates about the future of organ and tissue donation. This is unfortunate but perhaps not surprising. In the United States and elsewhere, these debates are dominated by the division between market- and gift-based exchange. Our stylized images of how these institutions ought to look (and how they should differ) lead us to assume more than we really know about the empirical cases. As a consequence, variation amongst actually existing procurement systems is not well understood, or simply not investigated. Instead, countries are classified as all being of the same gift-based type, and then contrasted with the supposed (usually hypothetical) commercial alternative. Thus, substantial differences in performance between countries are masked. Arguments about altruism versus self-interest and disputes over presumed and informed consent together constitute a good portion of the public discussion about organ donation. Yet neither debate helps us explain why some countries have many more organ donors than others. As best we can tell, countries with high procurement rates do not owe their success to any distinctive legal conception of consent, nor to any special way of institutionalizing exchange in human goods. Rather, more fine-grained organizational differences—specifically in logistics and process management—are responsible for their success.

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43. See Robert M. Sade et al., *Increasing Organ Donation: A Successful New Concept*, 74 *TRANSPLANTATION* 1142 (2002).

